

## **Remarks**

An IDS listing the references on a PTO-1449 form and a copy of each of the references was properly submitted on May 10, 2001. Applicant requests that the initialed form indicating that each of the references listed has been considered be included with the next Office Action or the Notice of Allowance. An additional copy of the PTO-1449 form has been submitted herewith for the convenience of the Examiner. Applicant requested a copy of the initialed PTO-1449 form in the last Response filed February 7, 2003; however, one was not returned in the last Office Action.

Claims 1-30, 32, and 34-54 are pending in the application. Claims 1-30, 32, and 34-54 stand rejected. Claims 1, 2, 9, 10, 11, 34, 35, and 40 are amended as above. New claims 55-61 have been added. Support for claims 55 and 56 can be found at page 13, lines 8-9. Support for claims 57 and 58 can be found at page 13, lines 14-15, and support for claims 59-61 can be found at page 12, line 21, to page 13, line 2. Applicant submits that no new matter has been added by these amendments. Applicant respectfully requests reexamination and reconsideration of the case, as amended. Each of the rejections levied in the Office Action is addressed individually below.

**I. Rejection under 35 U.S.C. §112, second paragraph, as being indefinite.** Claim 40 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has stated that “liquid” in claim 40 lacks antecedent basis. Claim 40 has been amended herewith to recite “fluid” instead of “liquid” since the term “fluid” is used in independent claim 35, from which claim 40 depends. Applicant submits that the amended claim 40 is definite having a proper antecedent basis for the term “fluid” and requests that the rejection be withdrawn.

**II. Rejections under 35 U.S.C. § 102.** Claims 32 and 34 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lina (U.S. Patent 6,468,237). Examiner maintains that Lina teaches a graded sequentially compressing device for treating patients with low blood flow and

wounds. Applicant disagrees because the disclosure only mentions in passing that “many aspects of this invention may be appreciated with other compression devices, possibly in combination with other intermittent or sequential compression features or devices.” Lina does not provide an enabling disclosure for combining sequential compression with the invention merely by reciting that it could *possibly* be combined with sequential compression. Lina does not actually teach one of skill in the art how this might actually be accomplished. Mere speculation by Lina that this might be possible does not constitute an enabling disclosure.

In addition, Lina does not teach that the compression is graded as claimed in the present application. The Examiner has pointed to the definition of “graded” in a dictionary; however, the dictionary definition of “graded” is not the definition the Applicant has relied upon in drafting the claims of the present application. Instead, Examiner is directed to page 7 where both the terms “graded” (please see page 7, lines 5-11) and “sequential” (please see page 7, line 17- page 2) are defined. Since the Applicant is allowed to be his or her own lexicographer, Applicant submits that the Examiner should interpret the claims using the definitions in the Specification rather than using the definitions found in a dictionary. The term graded is defined in the Specification as “a form of compression wherein the pressure applied at a distal region is greater than the pressure applied at a more proximal region.” Lina does not teach graded compression or even mention the term *graded* in U.S. Patent 6,468,237. Since Lina does not teach a limitation of the claimed invention, Lina cannot anticipate claims 32 and 34, and therefore, Applicant requests that the rejection be removed.

Claims 1, 9, 10, 13, 19-23, and 26 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Neeman *et al.* (U.S. Patent 5,014,681). Examiner submits that Neeman teaches a method of treating low blood flow comprising the steps of attaching a compression apparatus to a body part and applying graded sequential compression with a maximum pressure less than 200 mm Hg. Applicant disagrees because Neeman does not teach *graded* sequential compression, wherein the pressure applied at the distal region of the limb is greater than the pressure applied at a more proximal region (see page 7, lines 5-11, of the Specification). Although the Examiner has pointed to a definition of “graded” in Webster’s Dictionary, Applicant submits that this definition of graded is not relevant to the interpretation of the present claims given the definition

provided by the Applicant in the Specification. The Applicant's definition of graded is one commonly used in the art and is certainly not repugnant to the generally accepted meaning of the term; therefore, the claims must be interpreted in light of the Applicant's definition of graded. In order to anticipate a claim, the reference must teach every element of the claim. MPEP § 2131. Neeman does not teach this "graded" limitation of the present claims; therefore, Neeman cannot anticipate the claimed invention. Applicant requests that the rejection be removed.

Claims 1, 9, 10, 12, 13, 19, 20, 23, 25, and 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by McEwen *et al.* (U.S. Patent 5,843,007). Examiner states that McEwen teaches graded sequential compression. Applicant disagrees because McEwen fails to teach the graded aspect of the graded sequential compression. McEwen does not teach compression that is graded as this term is defined in the Specification on page 7-8. Since McEwen does not teach *graded* sequential compression of the present claims, Applicant submits that rejection should be removed.

Claims 35-37, 39, 40, 44, 47, 49, and 51-54 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zheng *et al.* (U.S. Patent 5,997,540). The Examiner states that Zheng teaches a device having a plurality of balloons, a peak pressure of 60 mm Hg, a computer, a blood oxygen detector, pulse oximeter, blood pressure detector, cooling means, and mounting means. Although Zheng may teach a device having all these components, Zheng does not teach a device including a control means that provides *graded* sequential compression as recited in the pending claims and as defined in the Specification. Examiner has pointed out that Zheng in column 8, lines 39-42 states that the balloons are sequentially inflated as the piston moves towards the second end of the cylinder. However, Examiner has pointed to no support in Zheng for the compression being graded as claimed in the present application. Since Zheng does not teach a device that can provide *graded* sequential compression, Zheng cannot anticipate the claimed invention. Applicant, therefore, requests that the rejection be removed.

**IV. Rejections under 35 U.S.C. § 103.** Claims 2-8, 11, 12, 14-18, and 27-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Neeman *et al.* (U.S. Patent 5, 014,681). Examiner states in his reasons for levying this rejection that the feature of using the compression

method to treat patients with such diseases and the maximum delivery pressure are an obvious design preference. The Examiner also states that Neeman's device would be able to perform the recited function of the present claims. However, this is not true. The present claims recite graded sequential compression. As described above, Neeman does not teach *graded* sequential compression as defined in the present application, and graded sequential compression could not be performed using Neeman's device. Neeman's device would not allow one to apply greater pressure at the distal region of the limb as compared to the proximal region. Therefore, without a teaching of *graded* sequential compression, Neeman cannot render obvious the claimed invention. Applicant requests that the rejection be removed.

Claim 13 stands rejected under 35 U.S.C. § 103 as being unpatentable over Neeman *et al.* (U.S. Patent 5,014,681) in view of Dillon (U.S. Patent 5,514,079). The Examiner uses Dillon to teach a pulse monitor having an EKG and a timer and concludes that it would have been obvious to one of ordinary skill in the art to provide Neeman's device with a pulse monitor as taught by Dillon in order to enhance the treatment effect. Although this may be true, Neeman and Dillon still do not teach graded sequential compression as described above. Since these references even when combined fail to teach or suggest this limitation of the present claims, they cannot render obvious the claimed invention. Therefore, Applicant requests that the rejection be removed.

Claims 1-12, 14-22, 24-30, 35, 41-46, 48, 50, and 52-54 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cariapa *et al.* (U.S. Patent 5,437,610). Examiner states that Cariapa teaches a hydraulic system including sequentially compressible bladders. Examiner, however, states that Cariapa does not teach the delivery of a maximum pressure of less than 300, 250, 200, or 150 mm Hg. Examiner maintains that choosing such a feature would be an obvious design choice. Applicant disagrees. The maximum pressure limitation is not an obvious design choice because Cariapa and the Applicant have two different goals in mind. Cariapa is using the device for treating edema while the present invention is directed to a method and apparatus for inducing angiogenesis or wound healing. In order to induce angiogenesis or wound healing, the endothelial cells of the patient must experience a change in shear stress, which may result from a higher maximum pressure than that needed to treat edema. Cariapa, since he was treating edema, would only need a pressure high enough to reduce edema and would not design his system to

induce a change in shear stress experienced by the endothelial cells of the patients. Typically, systems for reducing edema or preventing deep vein thromboses (DVTs) use pressures ranging from 20-50 mm Hg. The pressures needed in the claimed invention are higher and range from 75 mmHg to 300 mmHg. Since Cariapa does not teach pressures in this range, Cariapa cannot anticipate the claimed invention as amended.

In addition, one of ordinary skill in the art reading Cariapa would not be taught to search for a higher pressure that would induce angiogenesis or wound healing given the different goal of Cariapa—treating edema. The Examiner states that “it is well known in the art that using compressing devices to treat various diseases, and the patient receiving treatment must not exceed a safety range.” Applicant agrees that the claimed invention must not use pressures exceeding an acceptable safety limit; however, the pressures needed to reduce edema may be different than those needed to induce a change in shear stress experienced by the endothelial cells of the patients. Therefore, the pressures used in the presently claimed invention may fall within the acceptable safety range *and* be able to induce angiogenesis and wound healing. Even combining Cariapa with the notion that pressure cannot exceed safety limits does not provide a teaching or suggestion of the claimed invention. In addition, even if Cariapa were an invitation to try to such a method, there is no reasonable expectation of success given the disclosure in Cariapa. As evidence of this, Applicant was asked by the Examiner in the first Office Action to submit information supporting the utility and enablement of the claimed invention. Without a teaching or suggestion regarding the maximum pressure and a reasonable expectation of success, Cariapa cannot render the claimed invention obvious in inducing angiogenesis or wound healing.

Claim 38 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cariapa *et al.* (U.S. Patent 5,437,610) in view of Dillon (U.S. Patent 5,514,079). The Examiner has cited Dillon for teaching an EKG so as to provide better control during treatment. However, as described above, Cariapa does not teach the maximum compression pressure in the range needed to induce angiogenesis and wound healing as recited in the present claims, and Dillon does not teach this limitation even when combined with Cariapa. Since the references even when combined do not teach or suggest this limitation in the present claims, Applicant submits that the

combined references do not render the claimed invention obvious and requests that the rejection be removed.

In view of the forgoing amendments and arguments, Applicant respectfully submits that the present case is now in condition for allowance. A Notice to that effect is requested.

Please charge any fees that may be required for the processing of this Response, or credit any overpayments, to our Deposit Account No. 03-1721.

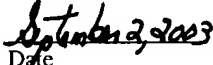
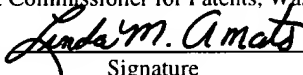
Respectfully submitted,



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Attachments: New set of Drawings (7 pages)